IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEBRASKA

ROBERT HOUSTON, as Personal Representative of the ESTATE OF RHONDA HOUSTON	§	
Plaintiff,	§	
VS.	§	NO. 8:09-cv-00306-LSC-FG3
	§	JURY TRIAL DEMANDED
MYLAN, INC., MYLAN PHARMACEUTICALS, INC., and MYLAN TECHNOLOGIES, INC.,	§	
Defendants.	§	

PLAINTIFF'S FIRST AMENDED COMPLAINT AND JURY DEMAND

Pursuant to Nebraska Code §§ 30-809 and 30-810, Plaintiff Robert Houston ("Plaintiff"), as Personal Representative of the Estate of Rhonda Houston, files this First Amended Complaint and Jury Demand against Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc. (collectively, the "Mylan Defendants") and for cause of action would show:

PARTIES

1. Plaintiff Robert Houston is an individual residing in Omaha, Nebraska. Plaintiff is the surviving spouse of Rhonda Houston ("Decedent") and the duly appointed personal representative of Decedent's estate. Under Nebraska Code §§ 30-809 and 30-810, Plaintiff brings this action on behalf of Decedent's Estate, on his own behalf as Decedent's wrongful death beneficiary, and on behalf of Decedent's other wrongful death beneficiaries, including, without limitation: (1) Seth Baldwin (Decedent's minor son) and (2) Katherine Edgington (Decedent's mother).

2. Defendant Mylan, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania. Mylan, Inc. has done and is doing business in Nebraska. Mylan, Inc. has been served and made an appearance in this lawsuit.

3. Defendant Mylan Pharmaceuticals, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the West Virginia. Mylan Pharmaceuticals, Inc. has done and is doing business in Nebraska. Mylan Pharmaceuticals has been served and made an appearance in this lawsuit.

4. Defendant Mylan Technologies, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the State of West Virginia. Mylan Technologies, Inc. has done and is doing business in Nebraska. Mylan Technologies has been served and made an appearance in this lawsuit.

JURISDICTION AND VENUE

5. Pursuant to 28 U.S.C. § 1332, this Court has jurisdiction over this case because it is a lawsuit between parties of diverse citizenship and the amount in controversy exceeds $75,000. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim (i.e., Decedent's fentanyl overdose and resulting death) occurred in this district.

FACTS

6. This suit arises out of the wrongful death of Decedent, due to the wrongful conduct of the Mylan Defendants. Decedent was given a prescription for 50 mcg fentanyl patches. The prescription was filled with 50 mcg Mylan (fentanyl transdermal system) patches from a

local pharmacy. Decedent was wearing one of these patches (the "Houston Patch") at the time of her death, and it was the cause of her death. The Patch worn by Decedent at the time of her death was designed, manufactured, marketed, and distributed by the Mylan Defendants.

7. The Patch is a matrix patch containing the drug fentanyl. Fentanyl is an extremely dangerous drug that is at least 80 times stronger than morphine. Fentanyl is classified as a Schedule II controlled substance by the FDA and is generally used to relieve pain.

8. The Patch is applied by the patient and delivers fentanyl though the patient's skin. The Mylan Defendants design, manufacture, market, and sell the Patch with the intention that it will release a certain amount of fentanyl into a patient at a certain rate, and thus produce a certain level of fentanyl in the blood of the patient. In other words, if a Patch functions as intended and it is properly used by the patient, the patient should not receive a harmful dose of fentanyl. Decedent never abused the Patch or used it inappropriately.

9. The Patch is unsafe for its intended or reasonably foreseeable use because it can and does cause lethal levels of fentanyl in patients. Prior to the time Decedent's patch was manufactured and distributed, numerous patients received lethal doses of fentanyl while using the Patch as prescribed. The Mylan Defendants knew or should have known that patients were receiving lethal fentanyl doses from proper use of the Patch because of wrongful death lawsuits filed against them, the FDA's adverse event reporting system, and adverse event reports from medical examiners and the World Heath Organization.

10. Decedent was prescribed Mylan 50 mcg patches for pain. Decedent died on September 10, 2007. Decedent had a fatal blood fentanyl level at the time of her death and the cause of

death listed on her death certificate is drug toxicity.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT PRODUCT LIABILITY
WRONGFUL DEATH

11. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

12. The Mylan Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement (Second) of Torts and/or § 6 of the Restatement (Third) of Torts. The Mylan Defendants at all times material hereto engaged in the business of designing, manufacturing, selling, marketing, and/or supplying the Patch, including the Houston Patch.

13. The Houston Patch was in a defective condition at the time it was designed, manufactured, sold, and/or marketed by the Mylan Defendants and at the time it left their possession because it was defectively manufactured, defectively designed, and contained insufficient warnings concerning its risks. These defects made the Houston Patch unreasonably dangerous (i.e., created a risk of harm beyond that which would be contemplated by the ordinary foreseeable user) for its intended or reasonably foreseeable use. The Houston Patch was unreasonably dangerous and, therefore, defective because, among other things, it gave Decedent a much higher dose of fentanyl than a properly functioning patch should have given her.

14. Decedent was unaware of the defective condition of the Houston Patch at the time she used the product in the manner and for the purpose it was intended. The defective condition was

a proximate cause of Decedent's death and the damages described herein.

15. The Houston Patch was in the control of the Mylan Defendants at the time the defect occurred. Further, the injury sustained by Decedent, fentanyl intoxication, was the exact type of injury that a defective Patch causes. The Houston Patch reached Decedent without any substantial change in its condition. The Houston Patch presented an unreasonable risk of injury because the risk was one which a reasonably prudent person having full knowledge of the risk would find unacceptable. Because of the nature of ingredients or natural characteristics of the Houston Patch, use of it involved a substantial risk of injury. The exposure to risk of injury was unreasonable taking into consideration a balancing of the dangers and benefits resulting from the product's use. Without limitation, the Houston Patch was defective because it malfunctioned and did not perform as intended and designed.

1. Manufacturing Defect

16. More specifically, the Houston Patch was defective because of the existence of a manufacturing flaw, which rendered the product unreasonably dangerous at the time it left the Mylan Defendants' control. The Houston Patch was unreasonably dangerous because it failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. The Houston Patch was unreasonably dangerous beyond that which would be contemplated by the ordinary foreseeable user. The manufacturing defect was a legal cause of Decedent's death and the damages claimed herein. Without limitation, the Houston Patch was defective because it malfunctioned and did not perform as intended and designed.

2. Failure to Warn

17. Pleading further and without waiver of the foregoing, the Houston Patch was defective because the Mylan Defendants failed to warn of risks that were known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time the Houston Patch was manufactured and distributed. The Mylan Defendants knew or had reason to know the Patch was or was likely to be unreasonably dangerous in the use for which it was made. Decedent was unaware of these risks, which were not readily recognizable by an ordinary consumer using the product in a reasonably foreseeable manner. The Mylan Defendants failed to warn Decedent or her doctor of the dangerous condition of the Houston Patch or that facts that made it dangerous. The Mylan Defendants' failure to warn was a proximate cause of Decedent's death and the damages claimed herein.

3. Design Defect

18. Pleading further and without waiver of the foregoing, the defective design of the Houston Patch made it unreasonably dangerous because it failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. The Houston Patch failed to comply with existing technology or the state of the art.

19. The Mylan Defendants, who participated in the design of the Patch, could have provided a safer alternative design. The foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design and the omission of the alternative design renders the product not reasonably safe. The safer alternative design, in reasonable probability, would have prevented or significantly reduced the risk of Decedent's death without substantially impairing the Patch's utility and was economically

and technologically feasible at the time the product left the control of the Mylan Defendants by the application of existing or reasonably achievable scientific knowledge. The design defect was a proximate cause of Decedent's death and the damages claimed herein.

SECOND CAUSE OF ACTION
STRICT PRODUCT LIABILITY
SURVIVAL ACTION

20. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

21. The defective condition of the Houston Patch was proximate cause of Decedent's conscious pain and suffering prior to death and the damages claimed herein.

THIRD CAUSE OF ACTION
NEGLIGENCE
WRONGFUL DEATH

22. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

23. The Mylan Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, sale, or distribution of the Patch into the stream of commerce, including but not limited to, a duty to assure that the Patch did not cause users to suffer from dangerous side effects, including death.

24. The Mylan Defendants knew or should have known that the Patch was or was likely to be dangerous (i.e., create a high risk of dangerous side effects, including death) when put to the use for which it was made. Further, the Mylan Defendants knew or had reason to know that patients and their prescribing doctors would not realize the danger. The Mylan Defendants failed to exercise reasonable care in the design, manufacture, marketing, testing,

approval, application for approval, inspection, sale, quality assurance, reporting to the FDA, quality control, and/or distribution of the Houston Patch to see that the patch was safe for the use for which it was made.

25. More specifically, the Mylan Defendants' negligence in the design, manufacture, marketing, testing, and sale of the Patch, includes but is not limited to the Patch's:

a. Providing misleading, inadequate, and/or insufficient warnings regarding the Patch to Decedent, a foreseeable user of the Patch, or to her prescribing doctor;

b. Failure to use due care in designing and manufacturing the Patch;

c. Failure to use proper materials reasonably suited to the manufacture of the Patch;

d. Failure to provide to the FDA information or data relevant to the safety of the Patch;

e. Failure to obtain easily accessible information or data relevant to the safety of the Patch;

f. Not performing sufficient testing of the Patch to confirm or ensure it was safe for its intended use;

g. Failure to use due care to test and inspect the Patch to determine its durability and functionality for the purpose for which it was intended;

h. Failure to ensure the Patch is made without defects;

i. Failure to conduct adequate testing and post-marketing surveillance to determine the safety of the Patch;

j. Misrepresenting that the Patch is safe for use;

k. Inadequate or insufficient inspection for defects;

l. Inadequate and/or insufficient research into the safety of the product prior to sale;

m. Inadequate and/or insufficient monitoring or research regarding adverse events;

n. Failure to list death as an adverse event;

o. Failure to provide adequate training, knowledge, or information to physicians, distributors, or sellers of the product;

p. Marketing the Patch for unsafe uses;

q. Failure to warn individuals adequately of the dangerous and lethal side effects of the product;

r. Formulating and designing the product;

s. Making the product;

t. Inspecting and testing the product; and/or

u. Packaging the product; and

v. Other and further particulars as will be proven at trial.

26. The negligent conduct of the Mylan Defendants, as alleged above, was a proximate cause of Decedent's death and the damages claimed herein.

FOURTH CAUSE OF ACTION
NEGLIGENCE
SURVIVAL ACTION

27. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

28. The negligent conduct of the Mylan Defendants, as alleged above, was a proximate cause of Decedent's conscious pain and suffering prior to death and the damages claimed herein.

FIFTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION BY OMISSION
WRONGFUL DEATH

29. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

30. The Mylan Defendants knew that the Patch created a high risk of unreasonable, dangerous side effects, including that proper use of the Patch can cause death, but Mylan failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public that proper use of the Patch could cause serious injury and/or death.

31. Therefore, Plaintiff brings this cause of action against the Mylan Defendants under the theory of fraudulent misrepresentation by omission for the following reasons:

a. The Mylan Defendants failed to warn of the defective condition of the Patch, as manufactured and/or supplied by the Mylan Defendants;

b. The Mylan Defendants, individually, and through their agents, representatives, distributors, and/or employees, falsely misrepresented material facts about the Patch in the course of their business in that they made such misrepresentations when they knew of the falsity of such misrepresentations. Alternatively, the Mylan Defendants made such misrepresentations recklessly without knowledge of the truth of the representations;

c. The above misrepresentations were made to the FDA, Decedent, physicians, pharmacists, as well as the general public;

d. The Mylan Defendants intended to induce others to rely on their representations, including, without limitation, Decedent, physicians, and pharmacists;

e. Decedent and others, including, without limitation, Decedent's physician(s) and her pharmacist(s), justifiably relied on the Mylan Defendants' misrepresentations; and

g. Consequently, Decedent's use of the Patch was to her detriment. The Mylan Defendants' fraudulent misrepresentations were a proximate cause of Decedent's death and the damages claimed herein.

DAMAGES

32. The unlawful acts and practices described above were a proximate cause of Decedent's death, her conscious pain and suffering prior to death, and the damages claimed in this lawsuit. Therefore, Plaintiff, on behalf of Decedent's Estate and Decedent's wrongful death beneficiaries, seeks all damages available under Nebraska law including, without limitation: (1) the loss of Decedent's likely future financial contributions; (2) the loss of Decedent's services; (3) the loss of Decedent's society, comfort, and companionship; (4) Decedent's conscious pain and suffering prior to death; and (5) Decedent's medical, funeral expenses, and burial expenses.

CONDITIONS PRECEDENT

33. All conditions precedent to Plaintiff's right to recover the relief sought herein have occurred or have been performed.

DEMAND FOR JURY TRIAL

34. Pursuant to Federal Rule of Civil Procedure 38, Plaintiff hereby demands trial by jury on all issues.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that the Mylan Defendants be cited to appear and answer, and that the Court set the case for jury trial, and that judgment be entered against the Mylan Defendants, jointly and severally, for the damages set forth herein above; for pre-judgment and post-judgment interest and costs of suit; and for such other and further relief to which Plaintiff may be justly entitled.

Respectfully Submitted,

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